

**The Subject Matter of Claim 4 is Fully Described in the
Specification as Filed**

Applicant respectfully disagrees with the Examiner's assertion the written description for the subject matter encompassed by claim 4 is inadequate. The Examiner, at page 3 of the Official Action, has indicated that an adequate written description and enabling disclosure of an invention is provided when "the claimed biological materials are (1) known and readily available to the public; (2) reproducible from a written description (e.g. sequenced); or (3) deposited". In the instance application, particularly at page 11, the specification has provided a detailed and reproducible description of how the claimed subject matter, i.e., NE-like cell lines including NE-1-9, were obtained. Specifically, the NE-1-9 cell line was obtained by a) seeding hormone-responsive human prostate cells in a normal medium; b) contacting the cells with and propagating the cells in a hormone-reduced medium; and c) isolating the NE-like cells that have survived in the hormone reduced-medium. Thus, cell line NE-1-9 has been fully described and enabled by the specification as filed. However, in order to expedite prosecution, Applicant hereby cancels claim 4, thereby rendering the rejection of this claim under 35 U.S.C. §112, first and second paragraphs, moot.

**The Application as filed Complies with the Requirements Set
Forth in 37 C.F.R. §§1.803-1.809**

It is the Examiner's position that the specification fails to provide an affidavit or declaration stating that all restriction upon public access to the deposits will be irrevocably removed upon the granting of a patent on the present application and that the deposit will be replaced if viable samples cannot be dispensed by the depository.

Applicant respectfully submits that such an affidavit or declaration is not required under 37 C.F.R. §§1.803-1.809. Particularly, as provided by 37 C.F.R. §1.803(a) that "[a] deposit shall be recognized for the purposes of these regulations if made in (1) [a]ny International Depository Authority (IDA) as established under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, ..." 37 C.F.R. §1.809(d) continues:

"For each deposit made pursuant to these regulations, the specification shall contain:

- (1) The accession number for the deposit;
- (2) The date of the deposit;
- (3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and
- (4) The name and address of the depository."

In the instance case, American Type Culture Collection (ATCC) is a depository authority established under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure and cell lines ~~NE-1-3 and NE-1-8~~ were deposited with ATCC under the Budapest Treaty. The ATCC accession number of the deposit, the date of the deposit, and the name and address of the depository, i.e., ATCC have been provided at page 10, lines 7-15 of the specification. Additionally, the specification also disclose methods of generating these cell lines and their characterization. Therefore, the specification has met the depository requirements set forth in 37 C.F.R. §§1.803-1.809.

To further demonstrate that cell lines NE-1-3 and NE-1-8 of the present invention have been deposited under the Budapest Treaty, Applicant hereby submit as Exhibit A a copy of the deposit form that was signed by the Applicant and sent to ATCC. Please note that on pages A6 and A8 of Exhibit A, the present inventor made the following statements under

points 9 and 13, respectively:

"After a U.S. patent issues and we are so notified, ATCC makes the culture available to anyone who requests it, as allowed under USPTO rules and Regulations (37 CFR 1.808[a][2]).

...

I understand and agree that the deposit may not be withdrawn by me for a period specified in Rule 9.1 of the Budapest Treaty (at least 30 years after the date of deposit or 5 years after the date of the most recent request for the deposit, whichever is longer), and that if a culture should die or be destroyed during the life of the patent or the period of time so specified, it is my responsibility to replace it with a living culture of the same organism or cell. In the cases of viruses, cell cultures, plasmids, embryos, and seeds, it is my responsibility to supply a sufficient quantity for distribution for the period of time specified above."

Based on all the foregoing, it is Applicant's position that the depository requirements have been met. Accordingly, the rejection of claims 2 and 3 on this ground is inappropriate and should be withdrawn.

The Metes and Bounds of Claims 2 and 3 as Amended are Clear

The Examiner states that claims 2-4 are "indefinite for the use of designation "NE-1-3, NE-1-8, NE-1-9" as the sole means of identifying the claimed cell lines." It is the Examiner's position that "the use of laboratory designation only to identify a particular cell line renders the claims indefinite." In response, claims 2 and 3 have been amended to recite the ATCC accession numbers of the claimed cell lines i.e., cell lines with ATCC accession Nos. PTA-3568 and PTA-3569. Support for this amendment can be found at page 10, lines 7-15. This amendment serves to clarify the metes and bounds of claims 2 and 3 and accordingly, Applicant requests that the rejection under §112, second paragraph be withdrawn.

Claims 2 and 3 are Enabled by the Specification

It is the Examiner's position that claims 1-4 encompass a human prostate cancer-associated NE-like cell line stored in any type of medium. The Examiner asserts that while being enabling for a cell line NE-1-3, NE-1-8, NE-1-9 stored in hormone deficient medium, the specification does not reasonably provide enablement for such cell lines stored in any type of medium. The Examiner's attention is directed to the Declaration of Dr. Lin, submitted herewith, providing data which demonstrate that the human prostate cancer-associated cell lines of the present invention are irreversibly differentiated NE-like cell lines which can be maintained for long periods in both hormone-containing and hormone-deficient medium. In light of the Declaration and data presented therein, the rejection of claims 2 and 3 under U.S.C. §112, first paragraph, should be withdrawn.

**Claim 1 is not Anticipated by Cox et al., or Burchardt et al.,
or Shen et al.**

Claim 1 of the present invention is drawn to a human prostate cancer-associated NE-like **cell line** comprising a homogeneous population of NE-like cells derived from hormone-responsive human prostate cells. As disclosed in the present specification, the claimed NE-like cell line is isolated from hormone-responsive human prostate cells that survive and proliferate in a hormone-reduced medium.

A cell line is defined in The Encyclopedia of Molecular Biology as follows: " A cell which will proliferate indefinitely in culture. Most cells isolated directly from non-embryonic tissues will only undergo a limited number of cell divisions in culture and thus cell lines cannot be established from them. Established cell lines are either

derived from a tumor (e.g., HeLa cells, Friend Leukemia cells) or embryonic tissues (e.g., BHK cells), or have become immortalized as a result of having undergone a transformation which causes the cell to behave in some respects like tumor cells (e.g., CHO cells). Numerous cell lines representing many different cell types have been established....."

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In order to constitute evidence of lack of novelty under 35 U.S.C. §102(b), a prior art reference must identically disclose each and every element of the rejected claim. In re Bond, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990). None of the references relied on by the Examiner teach **cell lines** having NE characteristics derived from a human prostate cancer cells. Indeed, each of the cited references teach that as LnCap cells differentiate into cells having an NE phenotype, such cells become non-mitotic, i.e., they stop dividing. See the abstracts of Cox et al. and Shen et al. Also see page 1801 first column of Burchardt et al. Thus, all three cited references teach that during the process of acquiring the NE cell phenotype, the cells lost mitotic activity and ceased cell growth. According to the definition provided above, none of the cited references teach the isolation and propagation of cell lines from such differentiated cells.

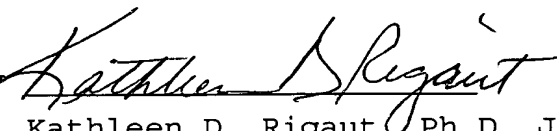
It is therefore submitted that none of the three cited references teach the NE-like cell lines of the present invention. Inasmuch as none of the recited references identically disclose the instantly claimed cell lines, withdrawal of the §102(b) rejection of claim 1 is respectfully requested.

CONCLUSION

In view of the Declaration of Dr. Lin attached hereto and amendments and remarks presented herewith, it is respectfully urged that the rejections set forth in the January 27, 2003 Official Action be withdrawn and that this application be

passed to issue. In the event the Examiner is not persuaded as to the allowability of any claim, and it appears that any outstanding issues may be resolved through a telephone interview, the Examiner is requested to telephone the undersigned attorney at the phone number given below.

Respectfully submitted,
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Enclosures: Declaration by Dr. Lin
Copy of ATCC Deposit Form
Definition of Cell Line